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The U.S. food and drug administration's regulation of brand and generic drug products

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This presentation will provide an introduction to the U.S. Food and Drug Administration's ("FDA") regulation of human pharmaceuticals including brand and generic drug products, the studies and clinical trials needed to support drug approval, the various components of a drug application, and post-marketing adverse event reporting. FDA's Center for Drug Evaluation and Research ("CDER" or "Center") is responsible for the regulation of pharmaceuticals including brand and generic drug products in the United States. CDER's duties include evaluating new drugs before they are marketed and sold; and then monitoring their safety once on the market. Before a drug can be tested in people, a company must perform laboratory and animal tests to discover how the drug works and whether it's likely to be safe and effective in humans. Next, a series of tests in people is begun to determine whether the drug is safe when used to treat a disease and whether it provides a real health benefit. A company then submits this information to CDER to show that the investigational product is safe and effective for its intended use. A team of CDER physicians, statisticians, chemists, pharmacologists, and other scientists reviews the submitted test data and the accompanying proposed labeling. If this independent and unbiased review establishes that the drug's health benefits outweigh its known risks, the drug is approved and permitted for sale in the U.S. CDER does not actually test drugs itself, although it does conduct limited research in the areas of drug quality, safety, and effectiveness standards.

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